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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ROBIN REESE, individually and on behalf of all others similarly situated,

Plaintiff,

vs.

ODWALLA, INC. and THE COCA-COLA COMPANY,

Defendants.

Case No. 13 Civ. 00947 (YGR)

JOINT NOTICE OF U.S. FOOD AND DRUG ADMINISTRATION GUIDANCE FOR INDUSTRY: INGREDIENTS DECLARED AS EVAPORATED CANE JUICE

Judge: Hon. Yvonne Gonzalez Rogers
Action Filed: March 1, 2013

Plaintiff Robin Reese ("Plaintiff") and Defendants Odwalla, Inc. and The Coca-Cola Company (together "Odwalla") submit this joint notice in accordance with the Court's April 13, 2016 Order, which directed that this case remain stayed pending the U.S. Food and Drug Administration's regulatory process regarding the term evaporated cane juice ("ECJ"). [Dkt. 79]. The FDA concluded its process on May 25, 2016, and published a revised Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, Dkt. No. FDA-2009-D-0430 ("2016 Final Guidance"). A true and correct copy of the 2016 Final Guidance is attached as Exhibit A.

In light of FDA's action, the parties agree that the stay that has been in place since March 25, 2014 should be lifted. The parties also agree that once the stay is lifted, the Court should proceed to rule on those aspects of Odwalla's original motion to dismiss ("MTD") that the Court did not reach after deciding to stay the case. The parties disagree, however, on the effect of the 2016 Final Guidance on Odwalla's arguments in support of dismissal.

Plaintiff's Position

As alleged in Plaintiff's Complaint [Dkt. 1], explained in Plaintiff's Memorandum in Opposition to Defendant's MTD [Dkt. 36], further explained in Plaintiff's Supplemental Memorandum [Dkt. 58], and now explained by the FDA in Exhibit A hereto, since 2000 the FDA has continuously and consistently stated that the use of "ECJ" as a euphemism for "sugar" in food label ingredient lists was and is misleading, and violates the "common or usual name" regulations. The FDA's policy was provided to the food industry in the FDA's May 8, 2000 Guidance Letter, again in the FDA's March 9, 2001 Guidance Letter, again in the FDA's October 2009 Guidance for Industry: Ingredients Declared as Evaporated Cane Juice ("2009 ECJ Guidance"), and repeated in several warning letters issued before and after the 2009 ECJ Guidance.[1] The FDA has never in the past 16 years exempted ECJ from the common or usual name regulations.

After the FDA reopened the comment period on the 2009 ECJ Guidance on March 4,

[1] The warning letters and the FDA's 2000 and 2001 Guidance Letters were included as Exhibits 2-7 of Plaintiff's Request for Judicial Notice [Dkt. 36-1]. The 2009 ECJ Guidance was included as Exhibit A to Defendant's Request for Judicial Notice [Dkt. 29].

2014, the Court asked for supplemental briefing on the applicability of the primary jurisdiction doctrine [Dkt. 57]. Plaintiff argued that the doctrine should not be applied due to the FDA's consistent and longstanding position that ECJ violated food labeling regulations, and that there was nothing in the notice announcing the comment period's reopening suggesting that the FDA was considering changing its guidance. Plaintiff observed that that, at most, the notice suggested that the FDA *might* reconsider the 2009 ECJ Guidance's suggestion that "dried cane syrup" might be an appropriate name for the ingredient. The Court, however, decided to wait for the FDA's decision.

In the interim the Ninth Circuit, in *Kane v. Chobani, LLC*, No. 14-15670, 2016 U.S. App. LEXIS 5517 (March 16, 2016) (unpublished), vacated the district court's order dismissing the [ECJ] complaint, and remanded with instructions to stay the action under the primary jurisdiction doctrine (with the proviso that the duration of the stay was subject to the district court's discretion).

Plaintiff's position concerning the FDA's policy proved to be correct. In its 2016 Final Guidance, the FDA once again reiterated its 16-year policy that "the term 'evaporated cane juice' is not the common or usual name of any type of sweetener" and that the ingredient should "be declared on food labels as 'sugar,' preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses (e.g., 'cane sugar')." Exhibit A at 4, 6. The FDA advised that "the term 'evaporated cane juice' describes neither the basic nature of the food nor its characterizing properties, and therefore does not comply with 21 CFR 102.5(a)," and stated that "the common or usual name for the ingredient currently labeled as 'evaporated cane juice"' includes the term 'sugar' and does not include the term 'juice.'" *Id*. at 6-7. The fact that, in 2014, the FDA asked the industry to identify data or other information that distinguished ECJ from other sweeteners that use the term "sugar" or "syrup" in no way suggests the FDA believed either the regulations or its prior guidance was ambiguous or in error.

Although the FDA's guidance documents do not have the force of federal law and thus could not have pre-empted Plaintiff's state law claims, *Reid v. Johnson & Johnson*, 780 F.3d 952,

964 (9th Cir. 2015), the FDA's 2016 Final Guidance powerfully re-confirms that Odwalla's argument - calling sugar ECJ does not violate the applicable regulations – is wrong. The 2016 Final Guidance reiterates what the FDA has been saying since 2000—ECJ is illegal because it violates the "common or usual name" requirement in 21 C.F.R. § 101.4, and the requirement in 21 C.F.R. § 184.1854 that sucrose be referred to as "sugar" on food ingredient labels.[2] *See* Exhibit A at 7. In addition, the use of ECJ in food ingredient lists violates regulations on what can be called "juice." *See* Exhibit A at 6-7. Finally, ingredient lists identifying sweeteners derived from sugars as ECJ are "false and misleading under section 403(a)(1) of the Federal Food Drug and Cosmetics Act (the "FDCA") (21 U.S.C. 343(a)(1)), because they do not accurately describe the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups as required by 21 CFR 102.5)." Exhibit A at 7.

Odwalla nevertheless argues that, in light of the 2016 Final Guidance, Plaintiff's Complaint should now be dismissed, because "the Sherman Law incorporates only binding FDA food labeling regulations," and "Plaintiff's claims under state law are preempted by the federal Food Drug and Cosmetic Act ("FDCA")." These arguments were and are incorrect, both before and after the 2016 Final Guidance. Odwalla is wrong for five reasons.

First, as explained in Plaintiff's Memorandum in Opposition to Odwalla's MTD [Dkt. 36], in the Sherman Law, Cal. Health & Safety Code § 110660, *et seq*., California expressly adopted the FDCA's labeling requirements as its own. Cal. Health & Safety Code § 110100 ("All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act . . . shall be the food regulations of this state.") Therefore, any violation of the FDCA or FDA regulations also violates the Sherman Law. *See* Dkt. 36 at 17-21.

Second, Plaintiff alleges that Odwalla violated binding regulations, including 21 C.F.R. § 101.4(a)(1), 21 C.F.R. § 184.1854, and 21 C.F.R. §102.5(a). *See* Dkt. 36 at 8-10. As noted

[2] As Plaintiff has asserted all along, the "FDA's food labeling regulations provide that sucrose obtained from sugar cane or sugar beets in accordance with 21 CFR 184.1854 *shall* be referred to as 'sugar' in ingredient labeling (21 C.F.R §101.4(b)(2))." Exhibit A at 7 (emphasis added). "Shall," is not "should" or "may."

above, the FDA's 2016 Final Guidance neither amends nor supersedes these regulations.

Third, though not displacing the regulations' binding requirements, courts give "wide deference to an agency's reasonable interpretation of its own regulation." *Public Lands for the People, Inc. v. United States Dep't of Agric*., 697 F.3d 1192, 1199 (9th Cir. 2012).). As the Ninth Circuit has held in the context of FDA food labeling guidance: "The FDA uses warning letters, among other enforcement measures, to police objectionable food and beverage labels in lieu of a preapproval process. Although 'informal and advisory,' the FDA issues warning letters to *obtain voluntary and prompt corrective action for what it considers to be significant violations* of the FDCA. The warning letters are publicly available on the FDA's website." *Reid v. Johnson & Johnson, et al.*, 780 F.3d 952, 962 (9th Cir. 2015) (emphasis supplied).[3] Here, deference is especially warranted given that the FDA has been remarkably consistent with respect to ECJ labeling for 16 years. The FDA's prior communications provided Odwalla clear and fair notice regarding improperly labeling ECJ, and its Final Guidance simply but powerfully re-confirmed that point. As in *Reid,* the FDA has made its position regarding ECJ known for "over a decade", *id.* at 966, and never revealed any "signs of backing away" from its position. *Id.*

Fourth, although Odwalla ignored the FDA's ECJ warning letters for more than a decade, Odwalla represents that it responded to Plaintiff's Complaint by removing ECJ labeling from some of its products. Even assuming the truth of that representation, Odwalla's belated compliance with existing Sherman Law requirements does not warrant dismissal of Plaintiff's Complaint.

Finally, Odwalla's three case citations are unavailing. *Wilson, Peterson* and *Eckler* did not involve alleged violations of 21 C.F.R. § 101.4(a)(1), 21 C.F.R. § 184.1854, and 21 C.F.R. §102.5(a), and are neither controlling nor persuasive. Odwalla does not – because it cannot - dispute that these regulations were binding law before and after the 2016 Final Guidance.

[3] At the same time, and as Plaintiff has previously explained, *Reid* also made clear that guidance documents do not have preemptive effect. *Id.* at 964. As Plaintiff previously explained, and reiterates below, the FDA only intended to issue revised draft guidance, rather than initiate a new rulemaking process and as such, would never have displaced the relevant regulations' binding effect.

Instead, Odwalla argues that the 2016 Final Guidance now exonerates its violations of those regulations. *Wilson, Peterson* and *Eckler* are district court opinions concerning the effect of guidance, not binding regulations. They provide no support for dismissal of a complaint that alleges violations of binding regulations that have remained unchanged, and have consistently been in effect. Stated differently, Odwalla's argument rests on the false premise that the fact that the FDA invited comment on ECJ therefore demonstrates that – akin to Odwalla's cited authorities – the FDA has expressly or impliedly suggested the relevant regulations are ambiguous. The FDA has made no suggestion. The regulations are clear, and the FDA's remarkably consistent guidance for 16 years only cements that fact.[4]

According to Odwalla, the question is: Did federal law prohibit ECJ labels *before* the 2016 Final Guidance was published, when certain Odwalla products bore ECJ labels? The answer is: Yes, it did, and the Court should deny Odwalla's MTD.

Odwalla's Position

In its original motion to dismiss, Odwalla demonstrated that Plaintiff's claims under California law fail as a matter of law, for two independent reasons: ***First***, Plaintiff's complaint fails to state a claim under California's Sherman Law because the Sherman Law incorporates only binding FDA "food labeling regulations" as "food labeling regulations of this state." ***Second***, because federal law at the time did not expressly prohibit ECJ labeling or require ECJ to be identified as something else, Plaintiff's claims under state law are preempted by the federal Food Drug and Cosmetic Act ("FDCA"). *See* Odwalla's Mot. to Dismiss [Dkt. # 28] ("MTD").

The Court did not reach either of these grounds for dismissal in light of its decision to stay

[4] Importantly, the FDA's March 2014 notice only expressed the FDA's intention to, if appropriate, issue revised draft guidance in accordance with FDA's good guidance practice regulations under 21 C.F.R. §10.115. The FDA never invoked, or even suggested it would initiate, its rulemaking process under 21 C.F.R. § 10.40 in connection with ECJ. That is in marked contrast to *Eckler,* where the FDA invoked its rulemaking process and ultimately issued a final rule. *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 437, 189 Cal. Rptr. 3d 339, 343 (2015), *review denied* (Oct. 21, 2015). Nor can Odwalla point to anything in the regulations at issue here that suggests that the underlying regulation was left open to various interpretations in a manner similar to that found by the *Wilson* and *Peterson* courts regarding "No MSG" statements; *Wilson*'s and *Peterson*'s debatable analyses aside, the issue of whether a label can claim the *absence* of an ingredient is an entirely different issue than *affirmatively* describing ECJ as "juice" instead of "sugar" or "syrup."

the case. Nevertheless, the Court's findings in support of the stay, and FDA's subsequent actions, leave no doubt that Odwalla's motion to dismiss should be granted. Specifically, when it ordered this case stayed, the Court found that federal law concerning ECJ was "unsettled," and that FDA's view on ECJ—reflected in a 2009 Draft Guidance to industry and several letters to companies—was "non-binding, and not legally enforceable." *See Reese v. Odwalla, Inc.*, 30 F. Supp. 3d 935, 942 (N.D. Cal. 2014). FDA confirmed these findings in 2014 when it reopened the notice and comment period on the 2009 Draft Guidance, stating that "We have not reached a final decision on the common or usual name for this ingredient."[5] *Id.* at 940.

Plaintiff filed her complaint in March 2013. The Court's findings and FDA's public statements confirm that, at that time, federal law did not definitively prohibit ECJ labeling. That is fatal to Plaintiff's case. As the Court previously observed, "Plaintiff's claims here are state law claims based upon the Sherman Law's incorporation of the FDCA's labeling requirements related to standards of identity and use of an ingredient's common and usual name." *Id.* at 941. Those FDCA requirements, however, were unsettled when Plaintiff commenced this action, and it would raise significant Due Process concerns if private plaintiffs were allowed to enforce unsettled federal requirements under California's Sherman Law. MTD at 12-13.

The Court also previously observed that Plaintiff's claims "turn, first and foremost, on whether" Odwalla's ECJ labels are "considered 'misbranded' under the federal food labeling laws, not on whether the labels are misleading in a general legal sense." *See Reese*, 30 F. Supp. 3d at 942. This is because "whether [a] label is misleading is governed entirely by its compliance with the federal regulations in this area," and "[f]ederal law completely displaces any non-

[5] The fact that FDA's position on ECJ was "unsettled" when Plaintiff filed her case makes this case distinguishable from *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. 2015). At issue in *Reid* were "No Trans Fat" and heart health claims for plant stanols. Unlike ECJ, FDA's position on these labeling practices was settled. FDA had previously considered whether to authorize "No Trans Fat" claims on food labels and "specifically declined" to do so. *Id*. at 962, 966. FDA also had previously considered heart health claims for plant stanols, and there was "already an interim final rule" on that subject "on the books." Id. Moreover, the labeling practices in *Reid* were not under active consideration or reconsideration by the agency. FDA had "shown no signs of backing away" from its stated position on trans fat claims. *Id*. at 967 & n.9. "Plus, it ha[d] been over a decade since the FDA indicated" that it might revisit its plant stanols rule. *Id*. at 966.

identical requirements in the areas covered by federal requirements." *Id.* Federal law did not impose a requirement that ECJ be identified as sugar (or anything else) when Plaintiff made her purchases or filed her complaint. Plaintiff's claims, accordingly, are preempted.[6] MTD at 8-9.

FDA's recent 2016 Final Guidance on ECJ does not change this analysis. As Odwalla explained in prior submissions in support of maintaining the stay, Odwalla voluntarily discontinued the use of ECJ on product labels in 2014.[7] [Dkt. #65] Plaintiff did not dispute this fact, and the Court cited it as a reason for maintaining a stay. [Dkt. #72] Thus, by the time FDA published the 2016 Final Guidance, which clarified the agency's interpretation of federal law, no Odwalla products on the market in the United States were labeled as containing ECJ.

The legal effect of the 2016 Final Guidance—and whether it enables private plaintiffs to pursue state-law claims against products that are currently labeled with ECJ—is a potentially complex question, but one that this Court need not reach. No Odwalla products are currently labeled with ECJ, and Plaintiff cannot in good faith allege otherwise. The legal question raised by Odwalla's motion to dismiss, therefore, is *not* whether the 2016 Final Guidance creates a prospective federal requirement that ECJ be identified by another name. The question is: Did federal law impose such a requirement *before* the 2016 Final Guidance was published, when certain Odwalla products bore ECJ labels? It did not.

This critical distinction is illustrated by recent decisions from three courts in California. *See Wilson v. Frito-Lay N. Am.*, 961 F. Supp. 2d 1134, 1147 (N.D. Cal. 2013); *Peterson v. Conagra Foods, Inc.*, No. 13-cv-3158-L (NLS), 2014 U.S. Dist. LEXIS 104073, at *12 (S.D. Cal. July 29, 2014); *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 189 Cal. Rptr. 3d 339 (2015). In *Wilson* and *Peterson*, plaintiffs filed suit against two food companies challenging "No MSG"

[6] Plaintiff confusingly asserts that FDA's guidance on ECJ cannot have preemptive effect because guidance documents do not have the force of law. Odwalla has never argued that Plaintiff's claims are preempted by FDA's guidance documents. Rather, Plaintiff's claims are preempted by the FDCA's express preemption clause, which preempts Plaintiff from seeking to impose labeling requirements regarding ECJ under state law that were not final or binding under federal law at the time of her purchases.

[7] Plaintiff speculates that Odwalla discontinued the use of ECJ labels in response to the filing of this lawsuit. This is incorrect. As explained in prior submissions, in a letter to FDA in 2013, Odwalla encouraged FDA to examine ECJ's common and usual name, but in an abundance of caution, informed the agency that it would voluntarily discontinue its ECJ labels.

claims on product labels after FDA in November 2012 published a guidance on its website stating that "No MSG" claims were not permitted if a food contains ingredients that may themselves contain MSG. The *Wilson* court held that the plaintiff's claims were *not* preempted as to products labeled with "No MSG" *after* November 2012 when FDA published its guidance. 961 F. Supp. 2d at 1147. But the court held the opposite as to products sold *before* November 2012 because, at that time, FDA's interpretation of federal law—which had been expressed in informal policy statements and warning letters to companies—was "ambiguous." *Id.*

According to the *Wilson* court, "To insist that Defendant should have been complying with a regulation that was not explicitly clarified until" November 2012 "would buck due process and Ninth Circuit precedent" barring enforcement of non-final federal requirements. *Id.* The *Peterson* court subsequently reached the same conclusion: "FDA's November 2012 [s]tatement regarding MSG clarified an ambiguous regulation. . . [However, b]ecause the labeling requirement imposed by state law is not identical to the FDA regulations before November 19, 2012, federal law preempts [plaintiff's'] claims before" that date. 2014 U.S. Dist. LEXIS 104073, at *12.

Eckler is to the same effect. There, the plaintiff sued under California law challenging "sunblock," "waterproof," and "sweatproof" claims on labels for the defendant's sunscreen products after FDA published a Final Rule in June 2011 requiring sunscreen makers to discontinue such claims by December 2012. 238 *Cal. App. 4th* at 456. The California appeals court held that the plaintiff's claims were preempted because, although FDA for years had raised significant concerns about these claims, FDA did not definitively interpret federal law to prohibit them "until the publication of the Final Rule on June 17, 2011," after which the defendant discontinued the claims. *Id.*

Plaintiff's attempts to distinguish *Wilson*, *Peterson*, and *Eckler* are unpersuasive. While none of those cases involved ECJ, the plaintiffs in *Wilson*, *Peterson*, and *Eckler* asserted that the defendants' labels violated *existing* FDA requirements, just as Plaintiff alleges here. The *Wilson* and *Peterson* defendants allegedly violated, among others, 21 C.F.R. § 101.22 (labeling of

spices), 101.22(h)(5) (common and usual name), and 101.21 (failure to reveal material facts). *See Peterson*, 2014 U.S. Dist. LEXIS 104073, at *8; Second Amended Class Action Complaint at 3, *Wilson v. Frito-Lay N. Am.*, No. 3:12-cv-01586-JST (N.D. Cal. May 1, 2013).[8] The *Eckler* defendant allegedly violated FDA's monograph for sunscreen products.[9] *Eckler*, 238 Cal. App. 4th at 455-56.

Moreover, in all three cases, the plaintiffs argued that their claims escaped preemption because the federal requirements that defendants allegedly violated "had been in place for decades" before their complaints were filed. *Wilson*, 961 F. Supp. 2d at 1146; *Eckler*, 238 Cal. App. 4th at 455-56 ("FDA banned the use of the terms long before" a final rule was published). The courts flatly rejected this argument. Although the federal regulations had been on the books for years, the plaintiffs' claims nevertheless were preempted because FDA's interpretation of those regulations, at least with respect to the label statements disputed in those cases, was informal and non-binding.[10]

Exactly the same is true here. It cannot seriously be disputed that the requirements of federal law with respect to ECJ were informal and non-binding prior to March 2016 when FDA published its final guidance. To allow Plaintiff to pursue claims concerning Odwalla products sold prior to March 2016 would offend Due Process. It also would retroactively create a requirement under state law that federal law did not impose at the time, which Plaintiff is preempted from doing. Plaintiff's claims, therefore, must be dismissed in their entirety.

Odwalla has also moved to strike (1) the complaint's nationwide class allegations, and (2) the factually baseless claims concerning Fanta Orange Zero, which never contained ECJ and

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[8] *See* Complaint, *Peterson v. Conagra Foods, Inc.*, No. 13-cv-3158-L (NLS), Dkt. #13 (S.D. Cal. July 29, 2014); *Wilson v. Frito-Lay N. Am.*, (N.D. Cal. 2013).

[9] *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 189 Cal. Rptr. 3d 339 (2015).

[10] Plaintiff asserts that FDA "continuously and consistently" disapproved of ECJ as a common and usual name. The relevant question, however, is not whether FDA's views were consistent, but whether FDA had made a final, binding determination that federal law prohibited ECJ labels. Plaintiff also asserts that courts generally give deference to an agency's interpretation of its regulations. But as *Wilson*, *Peterson*, and *Eckler* illustrate, whether an agency is entitled to deference is a distinct question from whether federal law ceases to carry preemptive effect. The latter occurs only once FDA had made a final determination as to what federal law requires.

Plaintiff did not allege she ever purchased. The Court should proceed to rule on these issues as well, to the extent they are not rendered moot by a ruling on the motion to dismiss.

DATED: July 25, 2016

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SIGNATURE CERTIFICATION

I hereby attest that I have obtained permission from Keith M. Fleischman and Joshua D, Glatter, counsel for Plaintiff Robin Reese, for the filing of this Joint Notice.

Dated: July 25, 2016

/s/ Steven A. Zalesin
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